Exhibit A

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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IN RE: '318 PATENT INFRINGEMENT : CIVIL ACTION
LITIGATION : NO. 05-356 (SLR)
: (Consolidated)

- - -

Wilmington, Delaware
Wednesday, April 18, 2007
3:00 o'clock, a.m.
Pretrial Conference

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge

- - -

APPEARANCES:

ASHBY & GEDES
BY: STEVEN J. BALICK, ESQ.

-and-

COVINGTON & BURLING
BY: GEORGE F. PAPPAS, ESQ.,
CHRISTOPHER N. SIPES, ESQ.,
KURT G. CALIA, ESQ.,
WILLIAM ZERHOUNI, ESQ. and
TRISHA B. ANDERSON, ESQ.
(Washington, D.C.)

-and-

Valerie J. Gunning
Official Court Reporter

APPEARANCES (Continued):

JOHNSON & JOHNSON
OFFICE OF GENERAL COUNSEL
BY: PATRICIA CLARKE LUKENS ESQ.
(New Brunswick, New Jersey)

Counsel for All Plaintiffs

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
BY: EDWARD V. FILARDI, ESQ. and
RACHEL BLITZER, ESQ.
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Counsel for Plaintiff Synaptech, Inc.
Only

RICHARDS, LAYTON & FINGER
BY: FREDERICK L. COTTRELL, III, ESQ.

-and-

CAESAR RIVISE BERNSTEIN COHEN & POKOTILOW, LTD.
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MONA GUPTA, ESQ. and
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(Philadelphia, Pennsylvania)

Counsel for Alphapharm Pty., Ltd.

PHILLIPS GOLDMAN & SPENCE, P.A.
BY: JOHN C. PHILLIPS, JR., ESQ. and
BRIAN FARNAN, ESQ.

-and-

APPEARANCES (continued):

WINSTON STRAWN, LLP
BY: GEORGE LOMBARDI, ESQ.,
TARAS A. GRACEY, ESQ. and
LYNN M. ULRICH, ESQ.
(Chicago, Illinois)

Counsel for Barr Laboratories, Inc.
and Barr Pharmaceuticals Inc.

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PROCEEDINGS

(Proceedings commenced in the courtroom, beginning at 3:03 p.m.)

THE COURT: And you all may be seated.

Why don't we start with introductions and then we'll talk about how we're going to use our time after that.

So let's start with plaintiffs' counsel.

MR. BALICK: Hello, your Honor.

THE COURT: Hello. How are you?

MR. BALICK: I'm fine. How are you?

THE COURT: I'm doing well.

MR. BALICK: Your Honor, for the plaintiffs from the Covington & Burling firm, George Pappas, Christopher Sipes, Chris Calia, William Zerhouni, Trisha Anderson. And seated next to her from Synaptech is the inventor, Bonnie Davis, Dr. Bonnie Davis.

THE COURT: Good afternoon.

MR. BALICK: And from the Skadden Arps firm, for plaintiff Synaptech, Edward Filardi and Rachel Blitzer.

THE COURT: Good afternoon. Thank you, Mr. Balick.

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work with plaintiff to come up with a way to resolve this issue and it is not -- it's not getting anywhere. And, unfortunately, it looks like we're going to have to do it through a deposition.

Dr. Rainer, he is in Austria. He has agreed to sit for a trial deposition in Austria on the issue of authenticating the documents that we'd like to put in front of him.

We could have tried to get this done when we listed him on the witness list. Your Honor's order indicated that deposition is the way to go. That wasn't even offered as an option to us.

We received a phone call about an hour before they filed their 60-page motion, asking if we would withdraw Dr. Rainer's name. We said we would not withdraw it. And then they filed a 60-page, what they call speaking motion, to exclude him.

We have not even had a chance to have discussion about having a deposition of this witness. Under your Honor's guidelines, this seems to fit exactly within what is contemplated by the rules.

And I'd like to address the letter that Mr. Pappas handed up.

First of all, I think it's inappropriate. This was not discussed with me. I was the author of that

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letter. This was not discussed. They asked for a response about a document that was inadvertently listed on defendants' exhibit list.

We responded within 24 hours and said, it was inadvertently listed. We would like the document back.

We've heard nothing. It has been -- tomorrow will be day 14. We have heard nothing from them.

The document they are referring to is a summary by a lawyer in Europe that was prepared at the request of patent counsel. Nobody sitting at this table, it has nothing to do with Dr. Rainer.

There was a German nullity proceeding in Austria. It's confidential to plaintiffs. We have no right to that information, so I don't know how Mr. Pappas can say we've known about something and then, in the other breath, he says you have no right to this information and neither do the witnesses because this is a closed proceeding. It's confidential. Nobody had access to this information.

So one doesn't square with the other. And frankly, I don't know what it has to do with anything. The reality is that plaintiffs were involved in a lawsuit with Waldheim. They know the ins and outs of that litigation better than we ever will. They have a relationship with Waldheim. They've been in

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correspondence with Dr. Rainer.

The notion that they could not have talked to him about this issue or sought him out themselves when his name has been raised time after time over two years of litigation is simply not credible.

And so, your Honor, we are asking for Dr. Rainer to be allowed to testify by a trial deposition, a very short deposition. It can happen as quickly as the next couple of weeks, if your Honor will allow it. And we can put this issue to rest.

And it does not have to be a side show is what I think, frankly, plaintiffs are trying to make it. This evidence, if it is admissible, it shows that somebody in addition to Dr. David had this idea. It's relevant to the level of skill in the art, and Mr. Pappas, if he has tried all the Hatch-Waxman cases he indicated, he knows that.

It's not just simultaneous invention. It goes to the level of ordinary skill and what was in that level of skill. That's an issue of dispute between the parties. There is no surprise as to that.

I will point out also that Dr. Rainer's position was articulated clearly in defendants' expert reports. Plaintiffs' experts chose to ignore it.

I took the deposition of a Dr. Cummings. I

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asked him, Did you look at these particular documents by Dr. Rainer? He said yes, he had looked at them. And I said, Does it change your opinion if, in fact, it's shown what Dr. Rainer is saying is true. His response was, It does not change my opinion.

So the notion that there has to be additional discovery or they need expert discovery, it simply is not true. Their expert opinion was, I looked at the material. It does not change my opinion at all. My opinion is what it is.

So, your Honor, for all these reasons, I request that we be allowed to have Dr. Rainer testify to authenticate the documents that plaintiffs claim they have serious concerns about.

THE COURT: All right. Thank you.

I don't need to hear anything before I ask some questions.

Ms. Ulrich, let me make sure I understand. It is my impression from reading the paper and from hearing the comments that the individual and the documents associated with the individual are not a surprise. I think we can all agree to that.

I think I glean from plaintiffs' presentation that the surprise is a new issue, a new defense, simultaneous invention.

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citations about why they believe it's obvious in light of the prior art. Nothing on simultaneous invention.

May 17th, 2006, we again, this time we, the plaintiffs, send not one, but a second set of interrogatories, and there, we ask the defendants, this is a -- extensive interrogatory.

I will sum it up for your Honor. We say, if you believe the patent is invalid for failure to satisfy Sections 101, 102, 103, 112 and 116, we're that specific, explain the basis for each belief according to its proof elements, as obvious reference the ones you rely upon, an explanation of the motivation of skill to combine, a description of all non-prior art defenses, such as lack of enablement, insufficient written description, failure to disclose best mode or claim indefiniteness, a description of the basis for any belief of improper or incorrect inventorship. And identify all the documents that relate to your contentions and the five most knowledgeable persons.

That day, their answer goes on for one, two, three, four, five, six, seven, eight, nine pages: Lack of written description, they contend. Lack of enablement. Obviousness, anticipation, simultaneous invention, nowhere.

THE COURT: And how about the argument that

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they are not -- I don't think they can claim simultaneous invention if, in fact, simultaneous invention was not -- well, let's assume they can't claim simultaneous invention because it wasn't formally and specifically noticed, but that this information is relevant in any event because it goes to the level of skill in the art, et cetera, the general background.

MR. PAPPAS: What that is, your Honor, with all due respect, I think that's what it's called in football a Hail Mary pass. That's an attempt to save what they've done.

They have Doctors Levy and Domino testifying about the level of skill of one of ordinary skill in the art. Those are the witnesses they have identified, put us on notice of and the ones that are going to testify about. They are not -- their purpose in trying to get this new issue into the case does not have anything to do with ordinarily skilled artisan testimony.

THE COURT: And if the -- if the experts relied on these documents to inform their idea or opinion about the level of skill in the art, which I understand they did.

MR. PAPPAS: Your Honor, we don't read their reports to be -- for that purpose. The purpose of them, the references in the expert reports after the close of

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fact discovery was some claim that they thought it had been simultaneously invented, but when asked about the documents they relied on by Mr. Sipes, they said, Well, we read these documents. We don't know if they are authentic and it is not the kind of material we would rely on in any event.

So it was, at best, a surface opinion. And in any event, your Honor, the problem here is that we have not, by not knowing that this was going to be an issue in the case, have not been given the opportunity to conduct discovery.

Let me focus, your Honor, please, on a very basic issue. Simultaneous invention, as your Honor knows, it's a fact question. It's not an expert opinion question.

If your Honor is ever called on in a patent case to determine who of two people invented, it's a fact question.

THE COURT: You're very good on your feet, Mr. Pappas, but I'm just -- I guess if -- this is my concern. Apparently, this evidence, the identity of the witness, these documents, have been known to all parties during at least part of this litigation. And so I want to make -- and so there is no surprise in terms of the identity of a witness or the identity of documents. And the question

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is: Are they relevant and was their relevance put at issue so that you had a fair and full opportunity to test their relevance.

Now, by labeling something simultaneous invention, I'm not -- I'm not sure how I go back and cobble where you all have been since I did not accompany you on this marvelous time you've had here in Court. I'm coming in at the tail end.

So what I'm going to do is I'm going to give each party -- first of all, I have to strike your motion from the record because if I don't, everyone will start filing motions in limine again. I'm sorry, but that's just the way you all are. But I'm still going to consider the merits of the issue because it was listed appropriately in your pretrial order.

I am going to give both parties the opportunity, within the next week, to show me, and it could be that I will just be getting the same documents, but I need to find out mostly from defendants at this point how it is that the purpose for which you wanted to use this evidence was specifically and formally put at issue in this case so that everyone knew it was at issue and everyone had a full and fair opportunity to test. All right?

I don't think I can resolve this today.

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Now, so I need you, Ms. Ulrich, to address that specific concern, because, clearly, in my cases, you do not raise a new issue after the close of discovery even if the witness who would testify about the issue has been known to everyone.

So that's -- as far as I'm concerned, that is the issue I need to address. And, once we resolve that, then the rest will follow.

MS. ULRICH: Sure. Your Honor, it's our position that it's not a new issue. This is not a new legal defense. The defense that we have is that the patent is obvious and that it's not enabled and that it's anticipated.

Those are the defenses we have set forth in our interrogatory answers that we have explained. We're not trying to inject a new defense here.

Dr. Rainer's testimony and the documents I would ask him to authenticate, to the level of skill -- the level of ordinary skill in the art. What was within that person's knowledge.

In some cases it's called simultaneous invention but most often you'll see it described, it's really probative of the level of skill in the art.

There was no interrogatory directed to the level of skill in the art. We explicitly disclosed this --

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I don't even want to call it a theory, because I don't think it is a theory. Disclosed this argument in our expert reports, which it took place, I think it was in the beginning of July or may have been the beginning of August of 2006. Multiple versions of reports went back and forth. Plaintiffs' experts had an opportunity to comment on that evidence. At no point did they say, Whoa, this is new. We have not heard this before.

The first time we heard them claim surprise, that we're somehow trying to inject a new theory into the case, frankly was when they filed a motion to exclude. And I was taken aback by that because, one, I don't know how they can claim unfair surprise. It has been known. Two, the words simultaneous invention, they are in transcripts before this Court. This issue has been talked about.

And so it's not -- we are not trying to inject a new theory into this case. It's a piece of evidence that supports the existing theory that we've had the from the beginning of this case, which is this patent is obvious and it goes to at least the level of skill in the art.

THE COURT: All right. My second question to you before I have a response from plaintiff is that if this witness, the only questions he will be asked basically

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are to authenticate the documents, then who is going to introduce the documents in terms of their relevance?

MS. ULRICH: The documents were relied on by -- by our experts in this case. The -- in addition to authenticating the documents, I'm sort of subsuming this within that, but we would try to lay the foundation for their independent admissibility.

We have reason to believe that these were business records of Dr. Rainer's and therefore would fall under the exception to the hearsay rule. But at the very least, these were already relied on by our experts. It really goes to the weight of the evidence in many ways.

For plaintiffs to come back and say to the expert, Well, you don't even know if this is authentic. It takes that issue off the table and it gives the Court assurances that what the expert is relying on is authentic and that whatever weight the Court wants to give to that is obviously within the Court's discretion. But we think it's at least fair. It would be manifestly unfair, frankly, not to have the person who could authenticate the documents do so when I hear plaintiffs saying they have serious concerns about the authenticity of these documents.

Frankly, I would think they would want them to be authenticated so these concerns would no longer exist.

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THE COURT: All right. Let's hear from you, Mr. Pappas.

MR. PAPPAS: Your Honor, let me address your first question. New issue, new defense.

On October 11th, 2005 -- and this is Exhibit B -- we specifically asked the defendants to set forth each of their bases for saying the patent was invalid. That's Interrogatory No. 2.

No. 3 says, Identify each witness you expect to call.

There is no mention of simultaneous invention, none. And there's no witness identified.

Then, on April 13, 2006 -- this is Exhibit G, there. And I think this is particularly telling, your Honor, about what is being done here, or attempting to be done. We asked in Interrogatory No. 2, separately for each claim, If you contend that any claim of '318 is invalid for failure to comply with one or more provisions for patentability, describe the basis for that contention.

Their response goes on for one, two, three, four, five, six, seven, eight pages. Nothing about simultaneous invention, nothing.

This is about an issue that wasn't raised. They go through great lengths about why Claim 1 and Claim 4 are anticipated. They go into great lengths with

Exhibit B

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April 5, 2007

VIA FACSIMILE & EMAIL
Mr. Kurt G. Calia
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004-2401

Re: In re '318 Patent Infringement Action

Dear Kurt:

I write in response to your April 4, 2007, letter to Taras Gracey regarding Defendants' Exhibit No. DX 576.

We have reviewed DX 576 and discovered that the document was inadvertently listed on Barr's Exhibit List. The document is privileged and work product. The document was prepared by European patent counsel, Bittner & Partner, at the request of Barr's patent counsel, in anticipation of litigation on the '318 patent. The document is Bittner & Partner's English summary of the October 1995 statement of defense filed by Synaptech in the German nullity proceeding involving Waldheim.

Thus, pursuant to paragraph 29 of the Stipulated Protective Order governing inadvertently produced documents, Barr requests that Plaintiffs return DX 576 (or certify to the destruction of all copies of the document). For its part, Barr will remove DX 576 from its Exhibit List.

Please let me know if you have any questions.

Very truly yours,

Lynn M. Ulrich

Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.,	
Plaintiffs/Counterclaim-Defendants,	C.A. No. 05-00381 (KAJ)
v.	**JURY TRIAL DEMANDED**
BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.,	
Defendants/Counterclaim-Plaintiffs.	

BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S RULE 26(a)(1) INITIAL DISCLOSURES

Pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure, Defendants-Counterclaim-Plaintiffs Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr"), without waiving any claim of privilege, work product protection, or other basis for non-disclosure, provide the following written statement of initial discovery disclosures. Barr reserves the right to supplement and/or amend these initial disclosures in accordance with the Federal Rules of Civil Procedure and the local rules of the Court and/or as investigation in this matter continues and new facts come to light.

Disclosures

A. Pursuant to Rule 26(a)(1)(A) of the Federal Rules of Civil Procedure, Barr identifies the following individuals or companies, with addresses and telephone numbers where known, who may have discoverable information that Barr may use to support its claims and defenses currently set forth in Barr's pleadings. The following list is not intended to be exhaustive. Barr's investigation continues. Barr will conduct additional searches should the

need for supplementary information arise and should a proper request be made in a timely manner. Barr reserves the right to amend and/or supplement its disclosures as the case progresses and discovery is taken.

Identity of Company and/or Individual	**Subject Matter**
Any individuals currently or formerly employed by : Janssen Pharmaceutica N.V. Turnhoutseweg 30, B-2340 Beerse, Belgium	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the sale of Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Any individuals currently or formerly employed by : Janssen, L.P. 1125 Trenton-Harbouton Road P.O. Box. 200 Titusville, NJ 08560	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the sale of Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Any individuals currently or formerly employed by : Synaptech, Inc. c/o Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the sale of Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.

Identity of Company and/or Individual	Subject Matter
Bonnie Davis 17 Seacrest Drive Huntington, NY 11743	Knowledge concerning, among other things, the alleged conception and reduction to practice of the invention allegedly claimed in the '318 patent; the claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
John Richards Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Lester Horwitz Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Joseph H. Handelman Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation,

Identity of Company and/or Individual	Subject Matter
	and Janssen's anticipated defenses to Barr's counterclaims in this litigation.

B. Pursuant to Rule 26(a)(1)(B) of the Federal Rules of Civil Procedure, Barr provides the following description by category and location of documents, data compilations, and tangible things that are in its possession, custody, or control that Barr may use to support its claims or defenses, unless solely for impeachment. By making these disclosures, Barr reserves the right to object to the admissibility, relevance, and the like of such documents and evidence. It is Barr's position that any documents produced before the entry of a Rule 26 Protective Order are to be treated in accordance with D. Del. Local Rule 26.1.

1. United States Patent No. 4,663,318;

2. Prosecution History of United States Patent No. 4,663,318;

3. Barr Laboratories, Inc.'s Abbreviated New Drug Application No. 76-605 filed by Barr Laboratories, Inc. with the FDA;

4. Rathmann, K.L. and Conner, C.S., "Alzheimer's Disease: Clinical Features, Pathogenesis, and Treatment," *Drug Intell. Clin. Pharm. 18*:684-91 (1984);

5. Cozanitis, D.A., "L'hydrobromide de galanthamine: un substitut du sulfate d'eserine (physostigmine) pour le traitement des effets cerebraux des substances anti-cholinergiques," *Nouv. Presse Med. 34*:4152 (1978); and

6. Any and all prior art or other documents identified by any Defendant in any of the related actions filed by Janssen in connection with galantamine hydrobromide.

Barr's counsel has a copy of the documents cited in categories (1) - (5) and has produced a copy of such documents to Janssen's counsel under separate cover on October 10, 2005. Barr notes that the documents in category 6 are publicly available. Barr reserves the right to supplement and/or amend these disclosures as necessary or appropriate in accordance with the

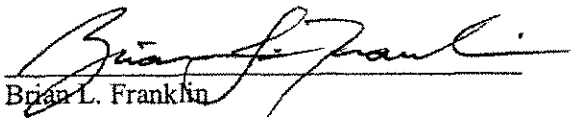
Federal Rules of Civil Procedure and the local rules of this Court and/or in response to specific discovery requests of Janssen.

C. Pursuant to Rule 26(a)(1)(C) of the Federal Rules of Civil Procedure, Barr discloses that it is seeking an award of attorneys' fees and costs. Barr will make available for inspection and copying, at the appropriate time, the documents and/or computations, together with supporting documents, concerning any claims for attorneys' fees under 35 U.S.C. 285, interest, and costs of this action. Barr reserves the right to seek additional damages from Janssen.

D. Pursuant to Rule 26(a)(1)(D) of the Federal Rules of Civil Procedure, Barr does not carry insurance coverage applicable to the claims raised in this lawsuit.

Date: October 10, 2005

BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.

By: 
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Attorneys for Defendants/Counterclaim-Plaintiffs Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

The undersigned attorney certifies that he caused a copy of the foregoing Rule 26(a)(1) Initial Disclosures of Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. to be served this 10th day of October, 2005, on the counsel of record by sending a copy by Federal Express to:

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George F. Pappas
Christopher N. Sipes
COVINGTON & BURLING
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Washington, D.C. 20004

Brian L. Franklin

Exhibit D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.,	
Plaintiffs/Counterclaim-Defendants,	C.A. No. 05-00381 (KAJ)
v.	**JURY TRIAL DEMANDED**
BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.,	
Defendants/Counterclaim-Plaintiffs.	

DEFENDANTS BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S OBJECTIONS AND ANSWERS TO PLAINTIFFS' FIRST SET OF INTERROGATORIES (Nos. 1-3)

Defendants/Counterclaim-Plaintiffs Barr Laboratories, Inc., and Barr Pharmaceuticals, Inc., (collectively, "Barr") by and through the undersigned attorneys and pursuant to Federal Rules of Civil Procedure 26 and 33, submit their Objections and Answers to Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V.'s, Janssen, L.P.'s and Synaptech, Inc.'s (collectively, "Plaintiffs") First Set of Interrogatories (Nos. 1-3). These Objections and Answers are based on information and documents presently available as a result of a search and review process that is continuing. Barr reserves the right to supplement and/or amend their answers as necessary or appropriate.

OBJECTIONS APPLICABLE TO ALL INTERROGATORIES

1. Barr objects to Plaintiffs' interrogatories to the extent that they:

(a) Seek information that is not relevant to any claim or defense raised

in this litigation, and are not reasonably calculated to lead to the discovery of relevant, admissible evidence;

(b) Seek information that is not in the possession, custody, or control of Barr;

(c) Seek information already known to Plaintiffs or available to Plaintiffs from documents in their own files, from public sources, or from the documents that have been produced in this case;

(d) Seek information subject to a confidentiality obligation of a nonparty to this lawsuit without prior consent of that nonparty;

(e) Seek information that is unreasonably cumulative or duplicative of other requests, or are obtainable from some other source that is more convenient, less burdensome, or less expensive;

(f) Seek production in this action of trade secrets or other confidential information before a protective order is entered by the Court;

(g) Seek information for which the burden or expense of production outweighs its likely benefit in resolving the issues of this action;

(h) Seek to impose discovery obligations upon Barr beyond those provided for by the Federal Rules of Civil Procedure and/or the Local Rules of this Court.

Barr objects to Plaintiffs' Interrogatories, including but not limited to the Definitions and Instructions, to the extent that they call upon Barr to disclose information protected from discovery because of the attorney-client privilege and/or the attorney work product doctrine, or because they otherwise call upon Barr to disclose the mental impressions, conclusions, considerations, opinions, or legal theories of attorneys or other representatives of Barr concerning this lawsuit. Any inadvertent production shall not be deemed a waiver of any

privilege with respect to such information or of any work product doctrine which may apply. Moreover, Barr objects to Plaintiffs' Interrogatories to the extent that they purport to request information and/or documents generated or dated after the filing of the lawsuit herein. Such information and documents will not be provided absent some agreement with Plaintiffs concerning what relevant and admissible documents, if any, are needed that would be dated after the filing date of the Complaint. Additionally, Barr does not intend to prepare a privilege log for any information or documents generated after the filing date of Plaintiffs' Complaint against Barr because doing so would be too burdensome given the active and ongoing involvement of attorneys. Plaintiffs should advise Barr if they object to this limitation.

2. Barr's investigation and discovery regarding facts relevant to this case are ongoing. Barr expressly reserves the right to supplement and/or amend these responses when their discovery and investigations are complete.

3. Barr objects to Plaintiffs' definition of the term "the '318 patent" as overly broad and not reasonably calculated to lead to the discovery of relevant, admissible evidence. Unless otherwise stated, for purposes of Barr's discovery responses, "the '318 patent" shall refer solely to U.S. Patent No. 4,663,318, issued on May 5, 1987, and *not* to "any foreign counterpart" of that patent.

4. Barr objects to those interrogatories which request the identity of "every person with knowledge" or include comparable requests, on the grounds that such requests are overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to these objections and as set forth in response to each interrogatory where applicable, Barr will identify those individuals who are the most knowledgeable or who have primary responsibility for the information requested.

SPECIFIC OBJECTIONS AND ANSWERS TO INTERROGATORIES

Interrogatory No. 1

Separately for each claim and each product, if you contend that any drug product containing galantamine or any salt thereof for which you are seeking FDA approval does not infringe any claim of the '318 patent, describe the basis for that contention.

ANSWER:

Barr, in addition to their general objections, objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome and seeks information not reasonably calculated to lead to the discovery of relevant, admissible evidence in that it seeks information regarding "any drug product containing galantamine or any salt thereof" when the only drug product at issue is the drug product that is the subject of Barr's ANDA No. 77-605, which is the subject of Plaintiffs' Complaint against Barr.

This Interrogatory also is overly broad because among other things, this Interrogatory seeks a response with respect to claims of the patent-in-suit that Plaintiffs have not identified are or would be infringed by the products that are the subject of Barr's ANDA No. 77-605 or by the manufacture, use, sale or offer for sale of the products that are the subject of Barr's ANDA No. 77-605. For example, Plaintiffs, despite repeated requests, refuse to specify which claims of the '318 patent allegedly are infringed by the products that are the subject of Barr's ANDA No. 77-605, and to provide, among other things, their claim construction of the asserted claims of the '318 patent. Plaintiffs have failed to identify these claims despite having received Barr's entire ANDA No. 77-605 on approximately June 4, 2005, and using that information to file their Complaint against Barr. Plaintiffs refusal to identify the claims that they are asserting against Barr is an unreasonable position given that under Rule 11 of the Federal Rules of Civil

Procedure, Plaintiffs must know what claims of the '318 patent they contend that Barr's ANDA products infringe or otherwise they are in violation of Rule 11.

Further, until such time as Plaintiffs identify which patent claims that they are asserting against Barr and what those claims mean, Barr objects to this Interrogatory as premature. Once Plaintiffs identify which claims of the '318 patent that they are asserting against Barr and provide their construction of these claims in response to Interrogatory No. 2 of Barr's First Set of Interrogatories served on September 15, 2005, Barr will supplement their answer to this Interrogatory with respect to the asserted claims of the '318 patent.

Barr further objects to the extent that this Interrogatory seeks to invade the attorney-client privilege or the work product doctrine.

Interrogatory No. 2

Separately for each claim, if you contend that any claim of the '318 patent is invalid for failure to comply with one or more of the provisions for patentability found in the U.S. Code, describe the basis for that contention.

ANSWER:

Barr, in addition to their general objections, objects to this Interrogatory on the grounds that it is overly broad and seeks information not reasonably calculated to lead to the discovery of relevant, admissible evidence. Among other things, this Interrogatory seeks a response with respect to claims of the patent-in-suit that Plaintiffs have not asserted are or would be infringed by the products that are the subject of Barr's ANDA No. 77-605 or by the manufacture, use, sale or offer for sale of the products in Barr's ANDA No. 77-605. Plaintiffs have failed to identify these claims despite having received Barr's entire ANDA No. 77-605 on approximately June 4, 2005 and using that information to file their Complaint against Barr. Plaintiffs' refusal to identify the claims that they are asserting against Barr is an unreasonable

position given that under Rule 11 of the Federal Rules of Civil Procedure, Plaintiffs must know what claims of the '318 patent they contend that Barr's ANDA products infringe or otherwise they are in violation of Rule 11. Until such time as Plaintiffs identify which patent claims that they are asserting and what those claims mean, Barr objects to this Interrogatory as premature. Once Plaintiffs identify which claims of the '318 patent that they are asserting and provide their construction of these claims in response to Interrogatory No. 2 of Barr's First Set of Interrogatories served on September 15, 2005, Barr will supplement their answer to this Interrogatory with respect to the '318 patent. Barr further objects to the extent this Interrogatory seeks to invade the attorney-client privilege or the work product doctrine.

Without waiving their objections, and subject to them, Barr responds that claims 1-7 of the '318 patent are invalid for obviousness under 35 U.S.C. § 103(a) in view of at least the following prior art references:

- Rathmann, K.L. and Conner, C.S., "Alzheimer's Disease: Clinical Features, Pathogenesis, and Treatment," *Drug Intell. Clin. Pharm. 18:684-91* (1984)

- Cozanitis, D.A., "L'hydrobromide de galanthamine: un substitut du sulfate d'eserine (physostigmine) pour le traitement des effects cerebraux des substances anti-cholinergiques," *Nouv. Presse Med. 34:4152* (1978)

The patentee did not cite, and the U.S. Patent and Trademark Examiner did not consider, any of these references, all of which were publicly available prior to January 15, 1998, and therefore constitute prior art under 35 U.S.C. § 102(b).

Barr reserves its rights, *inter alia*, to amend and/or supplement this response once Plaintiffs identify and construe the asserted claims of the '318 patent; to amend and/or supplement this response as discovery progresses in this litigation; and to rely on other prior art references identified by any other Defendant in any of the related actions filed by

Plaintiffs in connection with galantamine hydrobromide in support of Barr's invalidity claims.

Interrogatory No. 3

Identify each witness you expect to call at trial.

ANSWER:

Barr objects to this Interrogatory on the grounds that it is premature. Barr further objects to the extent that this Interrogatory seeks to invade the attorney-client privilege and/or the attorney work product doctrine. Without waiving their objections, and subject to them, Barr states that to the extent that they have so far identified any persons that they expect to call at trial as fact witnesses, such witnesses have been identified in Barr's Rule 26(a)(1) Disclosures, served on October 10, 2005. Barr further states that, they will provide their list of anticipated witnesses to Plaintiffs on a date directed by the Court or at least 30 days before trial, as required under Federal Rule of Civil Procedure 26(a)(3).

Date: October 11, 2005

BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.

By: Brian E. Farnan

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Attorneys for Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

The undersigned attorney certifies that he caused a copy of the foregoing Barr Laboratories, Inc.'s And Barr Pharmaceuticals, Inc.'s Objections And Answers To Plaintiffs' First Set Of Interrogatories (Nos. 1-3) to be served by hand on the 11th day of October, 2005 upon:

Steven J. Balick
ASHBY & GEDDES
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19801

and by Federal Express for delivery on the 11th day of October, 2005 upon

George F. Pappas
Christopher N. Sipes
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Brian E. Farnan

Exhibit E

12/20/2005 Telephone Scheduling Conference

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

IN RE: '318 PATENT INFRINGEMENT LITIGATION, : CIVIL ACTION : NO. 05-356 (KAJ) : (Consolidated)

- - -

Wilmington, Delaware
Tuesday, December 20, 2005 at 10:00 o'clock, a.m.
TELEPHONE SCHEDULING CONFERENCE

- - -

BEFORE: HONORABLE KENT A. JORDAN, U.S.D.C.J.

- - -

APPEARANCES:

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COVINGTON & BURLING
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Counsel for Par Pharmaceutical, Inc.
and Par Pharmaceutical Companies, Inc.

- oOo -

P R O C E E D I N G S

(REPORTER'S NOTE: The following scheduling conference was held in chambers, beginning at 10:00 a.m.)

THE COURT: Hi, this is Judge Jordan. I need to have whoever is on the line please introduce yourselves and name the party you represent.

MR. BALICK: Your Honor, good morning. For the plaintiff, Steve Balick locally; and also on the line from the Covington & Burling firm are George Pappas, Christopher Sipes and Laura McNeill; and from Johnson & Johnson, Steven Berman.

THE COURT: Okay.

MR. MATTERER: Good morning, Your Honor. This is Mary Matterer from Morris James representing Mylan; and we have also on the line Christine Siwik from the Rakoczy

say, Mr. Pappas, you never really figured there would be much of an infringement case anyway. But we started with a two-week trial. Now we have a stipulation regarding the accused products falling within or the ANDA falling within the scope of the claims and I'm still at a two-week trial based on the parties submission. And that's okay.

I'm leaving it on for two weeks, but I am moving this trial up. I'm going to move this trial up by a few months because I don't want -- and I'm starting to get the sense that part of the Court's scheduling mechanism might be being used in a bigger business sense. And that is, I'm not saying it's happening. I just get concerned about that. And it should not take as long to get this case ready for trial now.

So I'm moving this case up to June. I've got time to do it in June of '07 and I'm going to do it in June of '07. It's not as early as the defendants want but it's several months sooner in the game. And I'm not unsympathetic to the pressure that the impending change in the patent status has on the business planning. So I'm mindful of it and I'm making a shift.

And to the extent that there are problems with third-party discovery which were alluded to in Mr. Balick's letter, I just want to say, please, if you think you are going to need third-party discovery overseas -- this goes

for plaintiff and any of the defendants -- don't wait to do it. Here is a statement that plaintiffs may need to need the formal exchange of informal discovery. If that is true, I urge you to move forward on that as soon as possible so that if formal channels have to be dealt with instead of informal channels, we're not down the road months with a statement that we thought we could work it out and then it turned out we couldn't and now we have to go through the Hague Convention and now please extend discovery. That would be I think a mistaken way to approach it. It's better to have the formal processes working and then if something informal can be worked out, great.

Likewise, the assertions about discovery disputes which were in this letter, if you folks have discovery disputes and you can't work them out, bring them on. Give me a call. We'll set a time, we'll get things worked out. I would much prefer not to have discovery disputes at all, obviously, but I would rather deal with discovery disputes than not know about them and then months later here, now we need an extension in the schedule because we couldn't get cooperation.

So I expect all sides to cooperate reasonably. I'm not asking the defense to respond to the assertions made in the December 19th letter, but if it's in fact the case that you've been asked to produce all documents related to

Exhibit F

REDACTED

Exhibit G

REDACTED

Exhibit H

REDACTED

Exhibit I

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT LITIGATION	:	Civil Action No. 05-356 (KAJ) (Consolidated)

DEFENDANTS BARR PHARMACEUTICALS, INC.'S AND BARR LABORATORIES INC.'S SUPPLEMENTAL OBJECTIONS AND RESPONSE TO PLAINTIFFS' INTERROGATORY NO. 2

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Defendants Barr Pharmaceuticals, Inc. and Barr Laboratories, Inc. (collectively "Barr") supplement their response to Plaintiffs' Interrogatory No. 2. Barr reserves the right to supplement or amend its objections and response as it obtains additional information during the course of discovery.

GENERAL OBJECTIONS

The following general objections to Plaintiffs' Interrogatories (including Definitions and Instructions) are hereby incorporated into Barr's supplemental objections and response to Plaintiffs' Interrogatory No. 2 as if fully set forth therein.

1. Barr objects to Plaintiffs' Interrogatories to the extent they call for responses that would require disclosure of information that is protected by the attorney-client privilege, the attorney work-product doctrine, or any other evidentiary privilege.

2. Barr objects to Plaintiffs' Interrogatories (including Definitions and Instructions) to the extent that they purport to impose discovery obligations beyond those required under the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and any applicable Orders of the Court or agreements between counsel. Barr will follow the governing rules, orders, and agreements in

responding to these Interrogatories. Barr particularly objects to the Definitions and Instructions on these grounds to the extent that they call for response obligations beyond those required by Federal Rule of Civil Procedure 26(b)(1).

3. Barr objects to Plaintiffs' Interrogatories to the extent they are overly broad, unduly burdensome, and/or not reasonably calculated to lead to the discovery of admissible evidence.

4. Barr objects to Plaintiffs' Interrogatories to the extent an Interrogatory, or any words or terms used therein, is vague, ambiguous, subject to different interpretations, requires subjective knowledge by any party other than Barr, or involves issues of law subject to resolution by the Court. Barr will answer to the extent possible based on the most objectively reasonable interpretation of the Interrogatory.

5. Barr objects to Plaintiffs' Interrogatories to the extent they seek information beyond the possession, custody, or control of Barr, or to the extent the information requested is as readily available to Plaintiffs (or more so) as it is available to Barr.

6. Barr objects to Plaintiffs' Interrogatories to the extent they seek confidential or proprietary information of a non-party or seek highly confidential business or technical information that is of little or no relevance to the claims or defenses in this action.

7. Barr objects to Plaintiffs' Interrogatories to the extent that they are premature and Barr reserves the right to supplement its response pursuant to Federal Rule of Civil Procedure 26(e).

8. Barr objects to Plaintiffs' Interrogatories, including the Definitions and Instructions, to the extent they purport to define words or phrases in a manner different than their ordinary use, and Barr's response to such Interrogatories shall not be construed as an admission, agreement, or acquiescence in such a definition.

9. Barr objects to the definition of "you", "yours", and "Barr", and to those Interrogatories that incorporate these terms, to the extent that such terms are purported to include "all of Barr Pharmaceuticals, Inc.'s and Barr Laboratories, Inc.'s corporate parents, corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents and employees," or other non-parties to this case.

10. Barr objects to the definition of "Document" and to those Interrogatories that incorporate the term to the extent that Plaintiffs' definition of such term differs from the meaning or exceeds the scope of the usage of the term in Federal Rule of Civil Procedure 34(a).

11. Barr objects to the definition of "the '318 patent" and to those Interrogatories that incorporate the term to the extent that such term is purported to include "any foreign counterpart" to U.S. Patent No. 4,663,318 or any patents other than the patent asserted by Plaintiffs in the Complaint (*i e.*, U.S. Patent No. 4,663,318).

12. Barr objects to the numbering of the Interrogatories to the extent that particular interrogatories include discrete subparts that are not separately numbered. To the extent that the total number of interrogatories, including discrete subparts, exceeds the permitted number set forth in the Federal Rules of Civil Procedure, Barr reserves the right to refuse to answer all Interrogatories in excess of that number should the parties be unable to come to an agreement on the issue.

BARR'S SPECIFIC OBJECTIONS AND RESPONSE

INTERROGATORY NO. 2:

Separately for each claim, if you contend that any claim of the '318 patent is invalid for failure to comply with one or more of the provisions for patentability found in the U.S. Code, describe the basis for that contention.

RESPONSE:

Barr objects to this Interrogatory to the extent it seeks information relating to any claims other than claims 1 and 4 of the '318 patent, in light of the December 2, 2005 Stipulation Not to Contest Infringement. (*See* 12/2/2005 Stipulation, ¶ 4.) Barr objects to this Interrogatory to the extent this contention interrogatory is premature and may call for expert testimony. *See, e.g.*, Fed. R. Civ. P. 26(a)(2)(C). Barr objects to this Interrogatory as improperly being characterized as one interrogatory because its multiple subparts constitute separate interrogatories toward the presumptive 25 interrogatory limit. *See* Fed. R. Civ. P. 33(a). Barr notes that the Court has not yet construed any claim terms, phrases, or clauses of the asserted claims nor have Plaintiffs provided Barr with Plaintiffs' contentions as to the proper construction of any disputed claim terms, phrases, or clauses. Claim construction, which is an issue for the Court, is the first step in an infringement and/or invalidity analysis. Barr reserves the right to supplement this response on this basis and on the basis of any additional discovery consistent with the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and any relevant Orders of the Court. Barr further reserves the right to supplement its response to the extent that Plaintiffs change or otherwise supplement their contentions.

Subject to its general and specific objections, Barr responds to this Interrogatory as follows: Claim 1 of the '318 patent is directed to a "method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof." ('318 patent, claim 1.) Claim 1 is invalid under 35 U.S.C. § 102(b) as anticipated by at least P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1): 45-47 (1974) ("the Bhasker Article"). The Bhasker Article teaches treating "irreversible," "progressive

dementia," characterized by "a progressive fall-out of neurons and the course of the illness is rapidly downhill," with "small daily doses" of "Gallanthamine." One of ordinary skill in the art at the time of the invention would have understood the type of dementia described in the Bhasker Article to be or include at least Alzheimer's disease and/or related dementias. *See, e.g.*, K.L. Rathmann *et al.*, *Alzheimer's Disease: Clinical Features, Pathogenesis, and Treatment*, DRUG INTELL. CLIN. PHARM., 18: 684-91 (1984) ("the Rathmann Article") (teaches at least that Alzheimer's disease is a type of dementia); MERCK MANUAL (14th ed. 1982) (SYN RAZ 0006579-0006582) (teaches at least that Alzheimer's disease is a type of dementia "with a large loss of cells from the cerebral cortex and other brain areas," and that Alzheimer's dementia "progresses steadily."). One of ordinary skill in the art at the time of the invention would also have understood the Bhasker Article's "small daily doses" to be or include a "therapeutically effective amount." To the extent Plaintiffs contend any limitation of claim 1 of the '318 patent is not satisfied (and Plaintiffs have not to date), the claimed subject matter would have been obvious to one of ordinary skill in the art at the time of the invention in light of the Bhasker article alone, or in light of prior art articles or knowledge in the field as described further below.

Claim 4 of the '318 patent includes all of the limitations of claim 1 and further includes the limitations of "oral administration" in the range of "10–2000 mg per day." ('318 patent, claim 4.) Dosages within this range are a matter of routine experimentation and oral administration of galantamine[1] was well known. For example, claim 4 of the '318 patent is invalid as obvious, under 35 U.S.C. § 103 in view of the combination of the Bhasker Article and at least one of: D. Daskalov *et al.*, *Nivalin. Application and Rehabilitation Treatment of Cerebral Diseases with Aphasic Syndromes*, MBI MEDICO-BIOLOGIC INFORMATION, 3: 9-11

(1980) ("the Daskalov Article") (teaches at least oral administration of daily dosages of galantamine to humans in dosages including 10 mg, 15 mg, and 20 mg daily); and the Rathmann Article (teaches at least oral administration of daily doses of acetylcholinesterase inhibitors—a class of drugs including galantamine—to humans for treatment of Alzheimer's disease, and specifically administration of the acetylcholinesterase inhibitor physostigmine in dosages including 12–15 mg daily). The Bhasker article alone or in combination with at least one of the Daskalov Article and the Rathmann Article renders claim 4 invalid as obvious under 35 U.S.C. § 103 because one of ordinary skill in the art would have required only routine experimentation to determine dosages within the range of "10-2000 mg per day" of galantamine of claim 4, particularly in light of the extensive knowledge about galantamine's use in humans. In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to orally administer galantamine, as required by claim 4, and shown by the Daskalov Article.

Claims 1 and 4 of the '318 patent are also invalid as obvious under 35 U.S.C. § 103 in view of the combination of any two or more of: R.C. Mohs *et al.*, *Intravenous and Oral Physostigmine in Alzheimer's Disease*, INTERDISCIPL. TOPICS GERONT., 20: 150-152 (1985) (teaches at least administration of oral dosages of acetylcholinesterase inhibitors—specifically physostigmine—to humans for treatment of Alzheimer's disease in dosages including 12–24 mg per day); K.G. Pernov, *Nivalin and its Curative Effect upon Diseases of the Nervous System*, PSYCHIATRY AND NEUROLOGY AND MEDICAL PSYCHOLOGY BULLETIN ON RESEARCH AND PRACTICE, 13(11): 416-20 (1961) (teaches at least that galantamine hydrobromide and physostigmine—both acetylcholinesterase inhibitors—are chemically similar (*i.e.*, both are tertiary amines)); D.A. Cozanitis, *L'hydrobromide de Galanthamine: Unsubstitut du Sulfate*

[1] The terms galantamine and galanthamine are used interchangeably in the art.

D'eserine (Physostigmine) pour le Traitement des Effets Cerebraux des Substances Anti-Cholinergiques, NOUV. PRESSE MED., 7(45): 4152 (1978) (teaches at least that "galantamine hydrobromide . . . can have certain advantages over [physostigmine], due to its prolonged action," and that galantamine hydrobromide is able to cross the blood-brain barrier); UK Patent No. 942,200 (published 1963) (teaches at least that galantamine hydrobromide is "a strong anticholinesterase substance having an activity similar to that of [physostigmine], but showing a much less toxicity and a larger therapeutic range," and that galantamine hydrobromide acts on the central nervous system); B.S. Greenwald *et al*., *Experimental Pharmacology of Alzheimer's Disease*, THE DEMENTIAS, 87-102 (teaches at least that "[i]n every study in which multiple doses of a cholinomimetic agent have been administered to patients with AD, a positive effect of the drug has been noted," and that physostigmine's "relatively short duration of action renders it less desirable therapeutically in the long-term treatment on nonfluctuating clinical conditions, such as [Alzheimer's disease]") the Daskalov Article (teaches at least oral administration of daily dosages of galantamine to humans in dosages including 10 mg, 15 mg, and 20 mg daily); and the Rathmann Article (teaches at least oral administration of daily doses of acetylcholinesterase inhibitors—a class of drugs including galantamine—to humans in for the treatment of Alzheimer's disease, and specifically administration of the acetylcholinesterase inhibitor physostigmine in dosages including 12–15 mg daily).

Regarding claim 1 of the '318 patent, these prior art articles teach the use of acetylcholinesterase inhibitors—a class of drugs that includes physostigmine and galantamine—and physostigmine specifically, to treat Alzheimer's disease; that physostigmine has some drawbacks for treatment of Alzheimer's disease, including a relatively short duration of action; that galantamine hydrobromide and physostigmine are chemically similar (*i.e*., both are tertiary amines); that galantamine hydrobromide is a strong anticholinesterase substance having an

activity similar to that of physostigmine and can have certain advantages over physostigmine, including prolonged action, less toxicity, and a larger therapeutic range; and that galantamine, like physostigmine, was known to cross the blood-brain barrier. Consequently, it would have been obvious to one of ordinary skill in the art at the time of the invention to use galantamine to treat Alzheimer's disease and related dementias.

With respect to claim 4 of the '318 patent, these prior art articles additionally teach oral administration of both physostigmine and galantamine, and oral dosage ranges for both physostigmine and galantamine that fall within the claimed range of "10–2000 mg per day." Therefore, the claimed range of "10–2000 mg per day" of galantamine would have been obvious to one of ordinary skill in the art at the time of the invention. Additionally and/or alternatively, claim 4 is invalid as obvious under 35 U.S.C. § 103 because one of ordinary skill in the art at the time of the invention would have required only routine experimentation to determine dosages within the range of "10-2000 mg per day" of galantamine, as required by claim 4. Additionally, it is taught in the prior art and it would have been obvious to one of ordinary skill in the art at the time of the invention to orally administer galantamine, as required by claim 4.

Other prior art provides further support for Barr's contention that the '318 patent is invalid as being either anticipated under 35 U.S.C. § 102 (art reflecting knowledge in the field) or obvious under 35 U.S.C. § 103, including: A.R. Luria *et al.*, *Restoration of Higher Cortical Function Following Local Brain Damage*, DISORDERS OF HIGHER NERVOUS ACTIVITY, Ch. 21 (P.J. Vinken and G.W. Bruyn ed., North Holland Publishing Company 1969); B.S. Greenwald *et al.*, *Neurotransmitter Deficits in Alzheimer's Disease: Criteria for Significance*, J. AM. GERIATRICS SOC'Y, 31: 310-16 (1983); D.A. Cozanitis, *Galanthamine Hydrobromide, a Longer Acting Anticholinesterase Drug, in the Treatment of Central Effects of Scolpamine (Hyoscine)*, ANAESTHESIST, 26:649-50 (1977); L.J. Thal *et al.*, *Oral Physostigmine and Lecithin Improve*

Memory in Alzheimer Disease, ANNALS OF NEUROLOGY, 13:491-96 (1983); L.N. Nesterenko, *Influence Exerted by Galantamine on the Acetylcholinesterase Activity*, FARMAKOL TOKSIKOL, 28: 413-14 (1965); W. Göpel *et al.*, *Erfahrungen mit Nivalin in der Neurologischen Therapie*, PSYCHIAT. NEUROL. MED. PSYCHOL., 23: 712-18, (1971); C.M. Smith *et al.*, *Physostigmine in Alzheimer's Disease*, THE LANCET, 1: 42 (1979); R.C. Mohs *et al*, *Clinical Studies of the Cholinergic Deficit in Alzheimer's Disease*, J. OF THE AM. GERIATRICS SOC'Y, 33(11): 749-57 (1985); R.C. Mohs *et al*, *Oral Physostigmine Treatment of Patients With Alzheimer's Disease*, AM. J. OF PSYCHIATRY, 142(1): 28-33 (1985); V. Haroutunian *et al.*, *Cholinergic Modulation of Memory in Rats*, PSYCHOPHARMACOLOGY, 87(3): 266-71 (1985); K.L. Davis *et al.*, *Oral Physostigmine in Alzheimer's Disease*, PSYCHOPHARMACOLOGY BULLETIN, 19(3): 451-53 (1983); M.I. Levy *et al.*, *Research Subject Recruitment for Gerontological Studies of Pharmacological Agents*, NEUROBIOLOGY OF AGING, 3(1): 77-79 (1982); R. Yu. Il'yutchenok *et al.*, *Cholinergic Mechanisms of Memory: Analysis of the Amnesic Effect of Anticholinergic Drugs*, INT'L J. OF PSYCHOBIOLOGY, 2(3): 177-92 (1972); R. Yu. Il'yutchenok, *Pharmacological Aspects of Memory Neurochemical Regulation*, BULGARIAN ACADEMY OF SCIENCES: ACTA PHYSIOLOGICA ET PHARMACOLOGICA BULGARICA, 8(1-2): 43-49 (1982); V.A. Krauz *et al.*, *Role of Cholinergic Mechanisms in ATFase Activity and Glycolysis Intensity Regulation in the Rat Neocortex, Hippocampus and Truncus Cerebri*, FARMAKOLOGIA I TOKSIKOLOGIA, 1: 23-26 (1982); A. Plaitakis *et al.*, *Homer's Moly Identified As Galanthus Nivalis L.: Physiologic Antidote to Stramonium Poisoning*, CLINICAL NEUROPHARMACOLOGY, 6(1): 1-5 (1983); M. Bretagne *et al*, *Essais Cliniques en Anesthesiologie D'un Nouvel Anticholinesterasique la Galanthamine*, ANESTHESIE ANALGESIE REANIMATION, 1: 285-92 (1965); G. Milbled *et al.*, *Sur L'action Centrale de la Galanthamine*, COMPETES RENDUS DES SEANCES DE LA SOCIETE DE BIOLOGIE ET DE SES FILIALES, 160(11): 2089-90 (1966); R. Yu. Il'yuchenok *et al.*, *Comparison*

of the Effects Produced By Anticholinergic and Anticholinesterase Substances on Induced Potential of the Cerebral Cortex, FARMAKOLOGIA I TOKSIKOLOGIA, Vol. 1 (1969); R. Yu. Il'yutchenok, *Cholinergic Brain Mechanisms and Behaviour*, PROGRESS IN BRAIN RESEARCH: ANTICHOLINERGIC DRUGS AND BRAIN FUNCTIONS IN ANIMALS AND MAN, 28: 134-48 (1968); D.A. Cozanitis *et al.*, *A Comparative Study of Galanthamine Hydrobromide and Atropine/Neostigmine in Conscious Volunteers*, THE ANAESTHESIST, 416-21 (1971); K.L. Davis *et al.*, *Physostigmine: Improvement of Long-Term Memory Processes in Normal Humans*, SCIENCE, 201(4352): 272-74 (1978); K.L. Davis *et al.*, *Enhancement of Memory Processes in Alzheimer's Disease with Multiple-Dose Intravenous Physostigmine*, THE AM. J. OF PSYCHIATRY, 139(11): 1421-24 (1982); B.H. Peters *et al.*, *Effects of Physostigmine and Lecithin on Memory in Alzheimer Disease*, ANNALS OF NEUROLOGY, 6(3): 219-21 (1979); and Von K.G. Pernov, *Das Nivalin und seine Heilwirkung bei Erkrankungen des Nervensystems*, PSYCHIATRIE NEUROLOGIE UND MEDIZINISCHE PSYCHOLOGIE, 13(11): 416-20 (1961). Barr further reserves its right to rely upon any additional prior art identified by Plaintiffs, Barr, and/or any other Defendant against whom the '318 patent is asserted.

With respect to the issue of obviousness, Plaintiffs have to date identified no evidence in support of any secondary considerations of non-obviousness that affect the obviousness of the claims.

To the extent Plaintiffs contend that claims 1 and/or 4 are not anticipated or rendered obvious by the prior art, the claims are invalid for failure to satisfy the enablement requirement under 35 U.S.C. § 112, ¶ 1. "[T]o satisfy the enablement requirement of section 112, an applicant must describe the manner of making and using the invention 'in such full, clear, concise and exact terms as to enable any person skilled in the art . . . to make and use the same . . . .'" *See Rasmusson v. SmithKline Beecham Corp*, 413 F.3d 1318, 1322 (Fed. Cir. 2005)

(quoting 35 U.S.C. § 112, ¶ 1). In the case of determining the utility of a drug or medicament, to enable an invention, an inventor has to do more than "merely propos[e] an unproved hypothesis." *Id.* at 1325. Mere plausibility is not enough. *See Id.* "If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the 'inventor' would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis." *Id.* The '318 patent identifies no tests or studies in support of the claimed method of use, identifies no unknown property of the drug galantamine, and identifies no unknown scientific principle related to Alzheimer's or the effect of galantamine in the human body. "[W]here there is 'no indication that one skilled in the art would accept without question statements as to the effects of the claimed drug products and no evidence has been presented to demonstrate that the claimed products do have those effects,' an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement." *Id.* at 1323.

To the extent Plaintiffs contend Dr. Bonnie Davis invented anything not already known in the field, and therefore not anticipated under Section 102(b) nor obvious under Section 103, the '318 patent fails to provide an enabling disclosure and written description within the meaning of Section 112.

In addition, claim 4 is further invalid under 35 U.S.C. § 112, ¶ 1 because the inventor failed to teach one of ordinary skill in the art how to make or use the invention over the full scope of the recited range. Specifically, the specification does not teach one of ordinary skill that the entire recited range of "10-2000 mg per day" is a "therapeutically effective amount" as

required by claim 1. Therefore, claim 4 fails to provide both an enabling disclosure and an adequate written description under 35 U.S.C. § 112.

Respectfully submitted,

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BARR LABORATORIES INC.

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Attorneys for Defendants/Counterclaim-Plaintiffs Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.

Dated: April 13, 2006

CERTIFICATE OF SERVICE

The undersigned attorney certifies that he caused two copies of the foregoing Defendants Barr Pharmaceuticals, Inc.'s and Barr Laboratories, Inc.'s Supplemental Objections and Response To Plaintiffs' Interrogatory No. 2 to be served by hand on the 13th day of April, 2006 upon:

Steven J. Balick
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and by Regular U.S. Mail upon:

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COVINGTON & BURLING
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Washington, D.C. 20004

Brian E. Farnan

Exhibit J

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	))))	C.A. No. 05-356-KAJ (consolidated)

NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6)
TO BARR PHARMACEUTICALS, INC. AND BARR LABORATORIES

PLEASE TAKE NOTICE that on March 30, 2006 commencing at 9:00 a.m., at the offices of Covington & Burling, 1201 Pennsylvania Avenue, N.W., Washington, D.C. 20004, Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Plaintiffs" or "Janssen") will take the deposition upon oral examination of Defendants Barr Pharmaceuticals, Inc. and Barr Laboratories (collectively, "Barr") pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure. This deposition upon oral examination will be conducted before an officer authorized to administer oaths and will be recorded by stenographic and videographic means.

Plaintiffs serve this Notice without waiver of its objections to the deficiencies in Barr's document production and other discovery responses concerning the subject matter of the instant Notice, and reserve the right to continue this deposition as necessary in light of any subsequent document production by Barr.

Plaintiffs will take this deposition upon oral examination through one or more officers, directors, managing agents or other persons designated by Barr pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure as the person(s) knowledgeable to testify on Barr's behalf concerning the topics identified in Schedule A. Barr is requested to provide counsel for Plaintiffs with the identity of the individual(s) who will testify regarding each

topic at least one week in advance of the deposition. The deposition will continue from day to day until completed with such adjournments as to time and place as may be necessary. You are invited to attend and examine the witness(es).

ASHBY & GEDDES

/s/ Lauren E. Maguire

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Dated: February 21, 2006
166723.1

SCHEDULE A

Definitions

1. As used herein, "Barr" shall mean Defendants Barr Pharmaceuticals, Inc. and Barr Laboratories and all of Barr's corporate parents, corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents and employees.

2. As used herein, "Barr's ANDA" shall mean Barr's Abbreviated New Drug Application Number 77-605.

3. As used herein, "the Generic Product" shall mean the proposed generic galantamine product that is the subject of Barr's ANDA.

4. As used herein, "the '318 patent" shall mean United States Patent No. 4,663,318.

5. As used herein, "document" shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and shall include any means for retaining information.

6. As used herein, "FDA" shall mean the United States Food and Drug Administration.

7. As used herein, "Paragraph IV notice" refers to Barr's May 13, 2005 letter to Plaintiffs attached hereto as Exhibit 1.

8. "Person" and "persons" mean any natural person and any business, legal, corporate, or governmental entity, association, or organization.

9. "Alzheimer's Disease" means any diagnosis, illness, or ailment described as being of the Alzheimer's type, including without limitation Senile Dementia of the Alzheimer's Type, and/or Alzheimer's Dementia.

10. "Galantamine" includes without limitation galantamine, galanthamine, and any salt of galatamine, such as galantamine hydrobromide.

Topics of Examination

1. Barr's Paragraph IV notice including, without limitation, the meaning of, basis for, and any evaluation or analysis concerning the statement set forth in the letter that "Claims 1, 4 and 5 are obvious over Rathmann and Cozantis."

2. The names and responsibilities of all persons who were involved in any evaluation, consideration or discussion to develop the Generic Product conducted by or on behalf of Barr.

3. The decision to file an application with the FDA seeking approval to manufacture and sell a drug product containing galantamine.

4. The names and responsibilities of all persons who were involved in any evaluation, consideration or discussion to license or market the Generic Product conducted by or on behalf of Barr.

5. The benefits, including revenues and profits, that Barr projects, anticipates, expects, or forecasts it will obtain should Barr's ANDA receive approval from the U.S. Food and Drug Administration.

6. Marketing strategies, marketing plans, and projected sales for Barr's Generic Product.

7. Each and every contribution and/or input that Barr, or any employee or agent of Barr, has made to the preparation, decision to file, filing and/or prosecution of Barr's ANDA, including: (a) any information relating to regulatory procedures and strategies for obtaining regulatory approval of the Generic Product of Barr's ANDA; (b) any information comprising, relating to or contained in the 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certifications submitted in connection with Barr's ANDA; and (c) any information comprising, relating to

or contained in the statements of factual and legal basis for invalidity, unenforceability, and/or noninfringement included with the notice of these certifications.

8. The factual basis for Barr's proposed assertion that Barr's ANDA is indicated for the treatment of mild to moderate Alzheimer's disease.

9. The circumstances in which Barr first became aware of galantamine as a treatment for Alzheimer's disease, including but not limited to the date on which this occurred and the people involved.

10. The circumstances in which Barr first became aware of the '318 patent, including but not limited to the date on which this occurred and the people involved.

11. Any consideration or evaluation by Barr to develop a drug product containing galantamine for the treatment of Alzheimer's Disease.

12. Identification of all individuals, whether employees of Barr or third parties, having a role in the consideration or evaluation by Barr to develop a drug product containing galantamine for the treatment of Alzheimer's disease that is the subject of Topic 11, and a description of those roles.

13. Any effort by Barr to develop any drug product other than the Generic Product set forth in Barr 's ANDA.

14. Identification of all individuals, whether employees of Barr or third parties, having a role in the research, development or testing of such a treatment responsive to Topic 13, and a description of those roles.

15. The factual and legal bases for Barr's Affirmative Defense that all the claims of the '318 patent are invalid under one or more of 35 U.S.C. § 101, 102, 103, and 112.

16. The factual and legal bases for Barr's First Claim for Relief that the claims of the '318 patent are invalid according to its proof elements, including an element-by-element comparison of each asserted claim of the '318 patent to the prior art Barr relies upon and the motivation of one of skill in the art to combine any references under 35 U.S.C. §103, as well as a description of any non-prior art defenses such as lack of enablement, insufficient written description, failure to disclose best mode, or claim indefiniteness under 35 U.S.C. § 112.

17. The identity and location of documents and things concerning the foregoing topics.

18. Barr's document retention policies from 1986 to the present.

19. Persons knowledgeable about the subject matter of the foregoing topics.

166723.1

CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of February, 2006, the attached **NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6) TO BARR PHARMACEUTICALS, INC. AND BARR LABORATORIES** was served upon the below-named counsel of record at the address and in the manner indicated:

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/s/ Lauren E. Maguire

Lauren E. Maguire

Exhibit K

REDACTED

Exhibit L

REDACTED

Exhibit M

REDACTED

Exhibit N

REDACTED

Exhibit O

REDACTED

Exhibit P

REDACTED

Exhibit Q

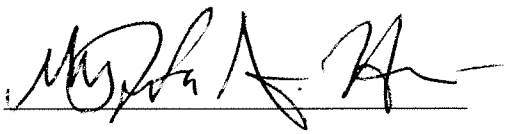
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE:	)	
'318 PATENT INFRINGEMENT LITIGATION	)	**Civ. No. 05-356-(SLR) (consolidated)**

DEFENDANTS BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S DISCLOSURE OF FACT WITNESSES

Pursuant to the Stipulated Order regarding the disclosure of fact witnesses entered into between the parties and filed with the Court on January 30, 2007, and pursuant to Judge Robinson's Standing Order, Barr Laboratories and Barr Pharmaceuticals ("Barr") identifies the following fact witness that they may call to testify on behalf of Barr: Mr. Paul Bisaro. By identifying this witness Barr is not required to call him at trial, either in person or by deposition.

In addition, Barr may call: (1) additional witnesses to provide foundational testimony should Plaintiffs contest the authenticity or admissibility of any materials to be proffered at trial; (2) any witness identified by Plaintiffs on their trial witness list; (3) substitute witnesses, to the extent that the employment of the abovementioned individual changes or the individual otherwise becomes unavailable for trial; (4) additional witnesses to respond to issues raised after the submission of this list, such as testimony of witnesses who have not yet been deposed; (5) any witness for purposes of impeachment.



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CERTIFICATE OF SERVICE

I hereby certify that on the 2nd day of February, 2007, I served the foregoing Defendants Barr Laboratories, Inc.'s and Barr Pharmaceuticals, Inc.'s Disclosure of Fact Witnesses on the following individuals as indicated below:

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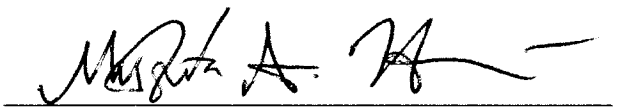

Mustafa A. Hersi

Exhibit R

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE:	)	
'318 PATENT INFRINGEMENT LITIGATION	)	**Civ. No. 05-356-(SLR)** **(consolidated)**

DEFENDANTS BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S DISCLOSURE OF REBUTTAL WITNESSES

Pursuant to the Stipulated Order regarding the disclosure of fact witnesses entered into between the parties and filed with the Court on January 30, 2007, and pursuant to Judge Robinson's Standing Order, Barr Laboratories and Barr Pharmaceuticals ("Barr") identifies the following rebuttal fact witnesses that they may call to testify on behalf of Barr: Messrs. Harry Boghigian, Timothy Sawyer, Matthew Zisk, Drs. Magid Abou-Gharbia, Kenneth Davis, Edward Domino, Gary King, Allan Levey, and Michael Rainer. Barr further reserves the right to call as witnesses at trial, either live or by introducing prior sworn deposition testimony, the corporate representative of any defendant named in this consolidated litigation who was previously deposed in this litigation. By identifying these witnesses Barr is not required to call such witnesses at trial, either in person or by deposition.

In addition, Barr may call: (1) additional witnesses to provide foundational testimony should Plaintiffs contest the authenticity or admissibility of any materials to be proffered at trial; (2) any witness identified by Plaintiffs on any of their trial witness lists; (3) substitute witnesses, to the extent that the employment of the abovementioned individual changes or the individual otherwise becomes unavailable for trial; (4) additional witnesses to respond to issues raised after

the submission of this list, such as testimony of witnesses who have not yet been deposed; (5) any witness for purposes of impeachment.

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Attorneys for Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 2nd day of March, 2007, I served the foregoing Defendants Barr Laboratories, Inc.'s and Barr Pharmaceuticals, Inc.'s Disclosure of Rebuttal Witnesses on the following individuals as indicated below:

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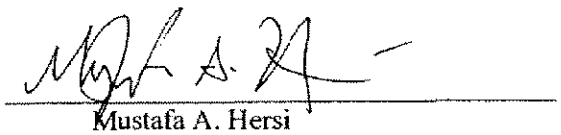

Mustafa A. Hersi